

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application Number : 10/815,995 Confirmation No.: 7292
Applicant : Edward M. SELLERS et al.
Filed : April 2, 2004
Title : THERAPEUTIC AND DIAGNOSTIC METHODS DEPENDENT
ON CYP2A ENZYMES
TC/Art Unit : 1614
Examiner: Unassigned

Docket No. : 62805.000041
Customer No. : 21967

Mail Stop Amendment

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

Sir:

In accordance with 37 C.F.R. §§ 1.97 and 1.98, and in compliance with the duty of disclosure set forth in 37 C.F.R. § 1.56, applicants are submitting herewith copies of the references listed on the attached Form PTO-SB/08A (modified) for consideration and to be made of record herein by the U.S. Patent and Trademark Office in the above-captioned application.

The subject application is a Divisional of U.S. Application No. 09/584,669 (Attorney Docket No. 62805.000020), filed June 1, 2000. In accordance with 37 C.F.R. § 1.98(d), patent documents and published articles which were cited in the prior application are listed on the accompanying Form PTO-SB/08A, but copies of these documents are not enclosed as they were provided in the prior application. However, copies will be forwarded at the request of the Examiner.

Consideration of the foregoing plus the prompt return of a copy of the enclosed Form SB/08A with the Examiner's initials in the left column in accordance with MPEP 609 are respectfully requested.

In accordance with 37 C.F.R. § 1.97(b), this Information Disclosure Statement is believed to be submitted prior to issuance of a first Office Action and within three months of the

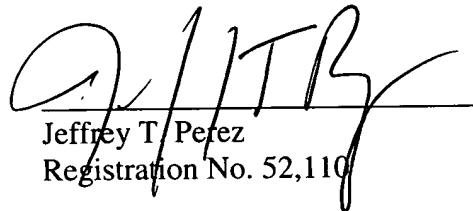
filings date of the application. Therefore, it is respectfully submitted that no fee is required for consideration of this information. However, in the event any fee is deemed necessary, the Commissioner is authorized to charge the undersigned's Deposit Account No. 50-0206.

Respectfully submitted,

HUNTON & WILLIAMS LLP

Dated: July 2, 2004

By:


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JTP/sdw

JUL 02 2004

PTO/SB/08A (10/01) (modified)

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Substitute for form 1449A/PTO

Application Number 10/815,995

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Filing Date April 2, 2004

First Named Inventor Edward M. SELLERS et al.

Art Unit 1614

Examiner Name Unassigned

Sheet 1 of 2 Attorney Docket Number 62805.000041

U.S. PATENT DOCUMENTS

| *Examiner Initials | Cite No. | DOCUMENT NUMBER Number - Kind Code (if known) | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear |
|--------------------|----------|--|--------------------------------|--|---|
| 1. | US | 5653987 | 08-05-1997 | Modi et al. | |
| 2. | US | 5760049 | 06-02-1998 | Viner | |
| | | | | | |
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FOREIGN PATENT DOCUMENTS

| *Examiner Initials | Cite No. | FOREIGN PATENT DOCUMENT | | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear | TRANSLATION | |
|--------------------|----------|-------------------------|----------------------------------|--------------------------------|--|---|--------------------------|--------------------------|
| | | Country Code: | Number - Kind Code (if known) | | | | YES | NO |
| 3. | WO | 95/34679 | 12/21/1995 | Jeffrey et al. | | | <input type="checkbox"/> | <input type="checkbox"/> |

NON-PATENT LITERATURE DOCUMENTS

| *Examiner Initials | Cite No. | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published | TRANSLATION | |
|--------------------|----------|--|-------------|----|
| | | | YES | NO |
| 4. | | NAKAJIMA, M. et al., "Characterization of CYP2A6 involved in 3'-hydroxylation of continine in human liver microsomes," J. Pharmacol. Exp. Therap., (1996) Vol. 277, No. 2, pp. 1010-1015 | | |
| 5. | | NAKAJIMA, M. et al., "Role of human cytochrome P4502A6 in C-oxidation of nicotine," Drug Metabol. Dospos., (1996) Vol. 24, No. 11, pp. 1212-1217 | | |
| 6. | | TSUJIMOTO, A. et al., "Potent inhibitory action of pilocarpine on hepatic drug metabolism," Jpn. J. Pharmacol., (1972) Vol. 22, No. 5, 736 | | |
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| 8. | | FOTH, H. et al., "Nicotine metabolism in isolated perfused lung and liver of phenobarbital-and benzoflavone-treated rats," Arch. Toxicol., (1991) Vol. 65, No. 1, pp. 68-72 | | |

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DATE CONSIDERED

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.



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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 2 of 2

Application Number 10/815,995

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| *Examiner Initials | Cite No. | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published | TRANSLATION | |
|--------------------|---|--|-------------|----|
| | | | YES | NO |
| 9. | KYEREMATEN, G. A. et al., "Metabolism of nicotine by hepatocytes," Biochem. Pharmacol., (1990) Vol. 40, No. 8, pp. 1747-1756 | | | |
| 10. | YAMAZAKI, H. et al., "Cytochrome P450 sE1 and 2A6 enzymes as major catalysts for metabolic activation of N-nitrosodialkylamines and tobacco-related nitrosamines in human liver microsomes," Carcinogenesis (1992) Vol. 13, No. 10, pp. 1789-1794 | | | |
| 11. | CAPLUS, DN 120:238085, Garnitskij et al., SU 1803032 A1, 1993/03/23, English abstract with notes from oral translation | | | |
| 12. | MAYS et al., Methoxsalen is a potent inhibitor of caffeine in humans, Clin. Pharmacol. Ther., 42:621-626 (1987) | | | |
| 13. | MAENPAA et al., "Metabolic interactions of methoxsalen and coumarin in humans and mice," Biochem. Pharmacol., 48(7), (1994), 1363-9 | | | |
| 14. | BENOWITZ, N. L. et al., "Deficient C-Oxidation of nicotine," Clinical Pharmacol. And Therap., 57(5):590-594 (1995) (Abstract) | | | |
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